UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,649	08/20/2003	David W. Robertson	00671.US1	8807

25533 7590 06/16/2005

PHARMACIA & UPJOHN
301 HENRIETTA ST
0228-32-LAW
KALAMAZOO, MI 49007

EXAMINER	
PRYOR, ALTON NATHANIEL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,649	ROBERTSON ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/22/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

$5.00

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 17-20 provides for the use of bupropion, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,9,17 are rejected under 35 U.S.C. 102(e) as being anticipated by Abuzzahab et al (US 20030092759; 5/15/03). Abuzzahab teaches a method treating restless limb syndrome comprising the administration to a patient a composition comprising bupropion. See abstract, page 3 lines 4-9, 27.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,9,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nofzinger et al (J. Clinical Psychiatry, 2000, 61(11), 858-62). Nofzinger teaches a method treating periodic limb movement disorder comprising the administration to a patient a composition comprising bupropion. Norfzinger teaches that bupropion is administered in slow release form. See abstract.

Claims 1-4,9,16,17,19 are rejected under 35 U.S.C. 102(b) as being anticipated by Billinghurst et al (EP 118036; 9/12/84). Billinghurst teaches a method treating dyskinesia (restless limb syndrome) comprising the oral administration to a patient a capsule composition comprising 5 to 95 % or 15–500 mg bupropion maleate. Capsulated forms of the active posses controlled release properties. See abstract, pages 4-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8,10,12-15,18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abuzzahab as applied to claims 1,9,17 above. Abuzzahab teaches all that is recited in claims 5-8,10,12-15,18,19 except for the method comprising the instant amount of bupropion, racemic bupropion, and (-) bupropion or its hydrochloric

acid salt. It would have been obvious to one having ordinary skill in the art to employ all isomeric forms of bupropion. One would have been motivated to do this because isomers are similar in structure and thus similar in activity unless shown otherwise by unexpected data. The bupropion and its HCl salt would have been expected to yield similar results since the compounds are structurally similar. With respect to the instant amount of bupropion, one having ordinary skill in the art would have been expected to determine the optimum amount. One would have been motivated to do this in order to make an invention that would have been most effective in treating restless limb syndrome.

Claims 5-8,10,12-16,18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nofzinger as applied to claims 1,9,17 above. Nofzinger teaches all that is recited in claims 5-8,10,12-16,18,20 except for the method comprising the instant amount of bupropion, racemic bupropion, and (-) bupropion or its hydrochloric acid salt. It would have been obvious to one having ordinary skill in the art to employ all isomeric forms of bupropion. One would have been motivated to do this because isomers are similar in structure and thus similar in activity unless shown otherwise by unexpected data. The bupropion and its HCl salt would have been expected to yield similar results since the compounds are structurally similar. With respect to the instant amount of bupropion, one having ordinary skill in the art would have been expected to determine the optimum amount. One would have been motivated to do this in order to make an invention that would have been most effective in treating periodic limb movement disorder.

Claims 5-7,9,11-14,16,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Billinghurst as applied to claims 1-4,17,19 above. Billinghurst teaches all that is recited in claims 5-7,11-14,20 except for the method comprising the instant amount of bupropion maleate, racemic bupropion maleate, and (-) bupropion maleate. It would have been obvious to one having ordinary skill in the art to employ all isomeric forms of bupropion maleate. One would have been motivated to do this because isomers are similar in structure and thus similar in activity unless shown otherwise by unexpected data. With respect to the instant amount of bupropion, one having ordinary skill in the art would have been expected to determine the optimum amount. One would have been motivated to do this in order to make an invention that would have been most effective in treating dyskinesia.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alton Pryor
Primary Examiner
AU 1616